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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/064,000	04/21/1998	JAMES P. ELIA	796-P-12	5311

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GERALD K. WHITE
LAW FIRM OF GERALD K. WHITE & ASSOCIATES, P.C.
205 W. RANDOLPH STREET
SUITE 835
CHICAGO, IL 60606

EXAMINER	
KEMMERER, ELIZABETH	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/064,000	ELIA, JAMES P.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *192-381* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *192-381* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 194,200-210,212,226,228-242,252,255,261-271,273,287,289-303,313,316,322-332,334,349,351-365 and 375.

Continuation of Disposition of Claims: Claims rejected are 192,193,195-199,211,213-225,227,243-251,253,254,256-260,272,274-286,288,304-312,314,315,317-321,333,335-348,350,366-374 and 376-381.

DETAILED ACTION

Election/Restrictions

Applicant's election of species c) of Part I (a living organism); and species 2 of Part II (non-resorbable carrier) in the election received 03 March 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further consideration, species o) and q) of Part I are rejoined to elected species c) of Part I. The elected invention will not be interpreted as being limited to mutlifactorial and nonspecific living organisms as per the second paragraph of p. 22 of the election received 03 March 2004, but will be interpreted as being directed to methods for producing a desired soft tissue in a body of a human patient comprising: (a) placing any living organism in said body of said human patient; (b) forming a bud in said body of said human patient; and (c) growing said desired soft tissue from said bud.

Claims 194, 200-210, 212, 226, 228-242, 252, 255, 261-271, 273, 287, 289-303, 313, 316, 322-332, 334, 349, 351-365 and 375 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the election received 03 March 2004.

Claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374 and 376-381 are under examination to the extent that they read on the elected species, i.e., a method

for producing a desired soft tissue in a body of a human patient comprising: (a) placing a living organism in said body of said human patient; (b) forming a bud in said body of said human patient; and (c) growing said desired soft tissue from said bud.

It is noted that Applicant indicated claims 192, 193, 195-199, 211-251, 253, 254, 256-261, 272-312, 314, 315, 317-321, 333-374, and 376-381 are readable on species c) of Part I and claims 192-225, 227-252, 253-286, 288-313, 314-348 and 350-381 are readable on said Species 2) of Part II. However, claims 212, 273 and 334 correspond to non-elected species p) of Part I; claims 228, 289 and 351 correspond to non-elected species 3) of Part II; claims 229, 290 and 352 correspond to non-elected species 4) of Part II; claims 230, 291 and 353 correspond to non-elected species 5) of Part II; claims 231, 292 and 354 correspond to non-elected species 6) of Part II; claims 232, 293 and 355 correspond to non-elected species 7) of Part II; claims 233, 294 and 356 correspond to non-elected species 8) of Part II; claims 234, 295 and 357 correspond to non-elected species 9) of Part II; claims 235, 296 and 358 corresponds to non-elected species 10) of Part II; claims 236, 297 and 359 correspond to non-elected species 11) of Part II; claims 237, 298 and 360 correspond to non-elected species r) of Part I; claims 238, 299 and 361 correspond to non-elected species s) of Part I; claims 239, 300 and 362 correspond to non-elected species t) of Part I; claims 240, 301 and 363 correspond to non-elected species u) of Part I; claims 241, 302 and 364 correspond to non-elected species v) of Part I; claims 242, 303 and 365 correspond to non-elected species w) of Part I; and claim 261 corresponds to non-elected species d) of Part I.

Status of Application, Amendments, And/Or Claims

The following papers from Applicant have been received and made of record in the instant case:

1) transmittal form, specification, claims, drawings, declaration and information disclosure statement filed 4/21/98;
2) change of address received 10/19/98;
3) petition for revival of 12/16/99;
4) amendment request for reconsideration filed 12/16/99;
5) revocation of power of attorney and appointment of new attorney received 1/3/01;
6) declarations by White, Isner, Wheeler, Meger, Lorincz and Finley, received 2/15/01;
7) amendment received 2/15/01;
8) information disclosure statement received 2/15/01;
9) declaration received 2/15/01;
10) formal drawings received 2/15/01;
11) information disclosure statement received 2/27/02;
12) information disclosure statement received 3/20/02;
13) amendment received 9/3/02;
14) information disclosure statement received 3/18/03;
15) information disclosure statement received 5/27/03;
16) amendment received 9/18/03 (copy of previously submitted amendment);
17) information disclosure statement received 11/28/03;
18) election received 2/24/04; and
19) election received 3/3/04.

All rejections of record are *withdrawn* upon further consideration and in view of the new grounds of rejection set forth below.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the elected invention to which the claims are directed.

Claim Objections

Claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374 and 376-381 are objected to because of the following informalities: the claims read on non-elected inventions. Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 216, 217, 277, 278, 338, 339, 340, 340 and 376-381 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 216, 217, 277, 278, 338, 339 and 376-381 read on methods of administering a living organism that is "multifactorial and non-specific". It is not clear what is meant by these terms, as the terms are not used to describe living organisms in the art. For example, the term "multifactorial" is used to describe causes, effects and processes, not living organisms. The specification also provides no clear definition. Therefore, the metes and bounds of the claims cannot be determined.

Regarding claims 340 and 340, claims are indefinite when they are numbered the same. In the interest of compact prosecution, the second occurrence of claim 340 is hereafter treated as claim 341; however, this treatment of the claims does not relive Applicant of the requirement to respond to the rejection.

35 U.S.C. §§ 101 and 112, First Paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374 and 376-381 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The claims, as they read on the elected invention, are generally directed to methods for producing a desired soft tissue in a body of a human patient comprising: (a) placing a living organism in said body of said human patient; (b) forming a bud in said body of said human patient; and (c) growing said desired soft tissue from said bud. Dependent claims specify the structure and/or function of the living organism, the carrier and the soft tissue. It is important to clarify on the record how the terms used in the claims are interpreted. Regarding "soft tissue," the specification includes tissues of mesodermal and ectodermal sources in the definition (p. 20). Mesodermal tissues include connective tissues, myoblasts, blood, the cardiovascular and lymphatic systems, most of the urogenital system, and the lining of the pericardial, pleural, and

peritoneal cavities (see Stedman's Medical Dictionary definition; Webster's Dictionary definition). Ectodermal tissues include skin and neural tissues (see Webster's Dictionary definition). "Soft tissue" is therefore being interpreted as any tissue that is not hard (bone). A 'living organism" is defined in the specification as including bacteria, viruses, or any other living organism which promotes tissue growth (p. 20). Webster's Dictionary defines an organism as a plant, animal or microscopic organism. Webster's Dictionary defines a microorganism as an animal or plant of microscopic size, such as a bacterium or a protozoan. The American Heritage Dictionary defines an organism as an individual form of life, such as a plant, animal, bacterium, protist, or fungus. Stedman's Medical Dictionary defines an organism as any living individual, whether plant or animal, considered *as a whole*. Perhaps most insightful is the discussion of living organisms by the Encyclopedia Britannica, which sets forth the seven functions of living organisms: movement, sensitivity, respiration, nutrition, growth, reproduction and excretion. At p. 8, the encyclopedia discusses how bacteria were once believed to be the simplest organisms, and that scientists still do not agree that viruses are living things since they cannot sustain life on their own. In view of these definitions, "living organism" as recited in the claims is interpreted as reading on animals, plants, bacteria and protists. It is important to note that a stem cell (one of the preferred embodiments of the application) is *not* a living organism. It is undoubtedly living, but it is a *part* of an organism, and not an organism *per se*. To consider a stem cell to be a living organism would be repugnant to the accepted meanings of the terms "stem cell" and "living organism" as

used in the art. Such is improper. See MPEP § 608.01(o). Also, the specification never states that a stem cell is a living organism.

There is no well-established utility, since the administration of living organisms to achieve soft tissue growth has never been achieved in this art. Although well-established utilities exist in predictable arts, such as mechanical or electrical arts, there can be no well-established utility in a complex system involving physiological responses in an absence of publications reporting similar results.

The asserted utility is not credible or substantial. One skilled in the art would not believe that a living organism could be administered to a human patient to achieve soft tissue growth. Administration of multicellular *living* organisms, such as animals and plants, is difficult to even envision. Administration of living microorganisms would be expected to result in infection and other adverse immunological effects. Also, the skilled artisan would not believe that a living organism would have the ability to promote soft tissue growth. Thus, the asserted utility is incredible. Clearly, significant further research would be required to identify living organisms, multicellular or unicellular, which could be administered to a human patient to achieve the required results. Achieving such would be considered part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. Applicant's attention is directed to Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct, 1966), in which the court held that the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374 and 376-381 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374 and 376-381 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Furthermore, it is appropriate to review the requirements for enablement, i.e., whether or not undue experimentation would be required of the skilled artisan to make and use the claimed invention. The courts have determined several factors to be considered in making a determination of whether or not undue experimentation would have been required of the skilled artisan to make and use the claimed invention (*In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). These are:

1) quantity of experimentation required,

2) amount of direction/guidance presented in the specification,

3) presence or absence of working examples,

4) nature of the invention,

5) state of the prior art,

6) level of skill of those in the art,

7) predictability, and

8) breadth of the claims.

1) In the instant case, the quantity of experimentation required would be very large. Administration of living organisms to a human patient to produce soft tissue has not been achieved in this art. One skilled in the art can envision all sorts of difficulties which must be overcome before such can be achieved. For example, how can a living, multicellular organism be administered at all? How can a living microorganism be administered to achieve soft tissue growth without immune response (i.e., infection)? What living organisms are capable of promoting tissue growth? Neither the art nor the specification indicate what living organisms have the required properties, or how to

overcome these substantial obstacles. Thus, a large amount of experimentation would be required to successfully practice the claimed methods.

2) The amount of direction or guidance in the specification is very limited. The specification asserts that bacteria and viruses can be administered to achieve soft tissue growth. However, there is no guidance regarding what types of living organisms have the ability to promote soft tissue growth. There is no guidance regarding how to administer a living organism of any sort without inducing adverse immune responses (e.g., infection).

3) There are no working examples, real or prophetic, directed to the administration of living organisms.

4) The nature of the invention is highly complex. All inventions involving administration of active agents of any kind to a patient to achieve a physiological reaction are complex.

5) The state of the prior art indicates that there have been no attempts to administer living organisms to achieve soft tissue growth. Several groups have administered stem cells with some effect. See Strauer et al. (2002, Circulation 106:1913-1918), who report that administration of bone marrow cells appeared to promote myocardial regeneration and neovascularization. However, stem cells are not living organisms, and thus this report does not support enablement of the elected invention. Murry et al. (1996, Clin. Invest. 98:2209-2217) report induction of skeletal muscle differentiation in hearts that have been treated with a replication-defective adenovirus containing a MyoD gene. Replication-defective adenovirus is also not a

living organism, since it has been modified to destroy its ability to replicate or reproduce, a required function of any living organism. Therefore, Murry et al. also do not support enablement f the elected invention. Morishita (2002, Circ. J. 66:1077-1086), Khurana et al. (2001, Hypertension 38 :1210-1216), Isner et al. (2001, Circ. Res. 89:389-400), Hajjar et al. (2000, Circ. Res. 86:616-621) and Kullo et al. (1999, Arterioscler. Thromb. Vasc. Biol. 19:196-207) provide reviews of methods used to achieve soft tissue growth in damaged heart tissue. While some success was reporter using isolate eukaryotic cells (which are parts of living organisms but not organisms *per se*), genes, and proteins, no research group even attempted administering an independent, living organism to achieve soft tissue growth.

6) The level of skill in the art is admittedly high.

7) The invention is unpredictable, as it involves administering active agents to a living patient to achieve a physiological response. As was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), most chemical reactions and physiological activity involve unpredictable factors. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

8) The breadth of the claims is quite large. As reviewed above, growth of virtually any type of tissue other than bone is encompassed by the claims. The administered agent is a living organism of any sort, including multicellular organisms or microorganisms.

According to the courts, tossing out the mere germ of an idea does not constitute an enabling disclosure. Reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. See Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ.2d 1001 (1997). The instant specification contains only a couple of sentences asserting that living organisms can be administered to achieve soft tissue growth. No details as to how to accomplish this are given. Thus, Genentech v. Novo Nordisk A/S, *supra*, is relevant. Vague intimations of general ideas that may or may not be workable do not constitute an enabling disclosure. See Genentech Inc. v. Novo Nordisk A/S, *supra.*

Due to the large quantity of experimentation necessary to determine how to effectively administer living organisms to achieve growth of soft tissue in a human patient, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, the contradictory state of the prior art, the unpredictability of the effects of any agent on a physiological response, and the breadth of the claims which fail to recite limitations regarding cell type or dosage or site of delivery, etc., undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Response to Applicant's Arguments

Applicant provided arguments pertaining to the previous utility and enablement rejections in responses received 16 December 1999 and 15 February 2001. Applicant's arguments, insofar as they pertain to the instant rejections, will be addressed.

In the response of 16 December 1999, Applicant quotes from the specification that the administered agent can be a living organism (p. 20 of the specification). Applicant refers to a Scientific American article published in 1999 as providing evidence that the use of genetically produced material to grow organs was known in 1993. Applicant refers to the Isner patent (US 5652225) as providing evidence that growth of blood vessels with genetically produced material has been accomplished. Applicant's arguments have been fully considered but are not found to be persuasive. The quote from p. 20 of the specification adds nothing to the record. Although the specification asserts that living organisms can be administered, it provides no guidance regarding what types of living organisms have the capability of promoting soft tissue growth, or how to administer a multicellular living organism, or how to administer a microorganism while avoiding infection or other adverse immunological effect. The Scientific American article and the Isner patent do not disclose administration of living organisms to promote soft tissue growth, and thus do not support utility or enablement of the elected invention.

In the response of 15 February 2001, Applicant provides declarations of four medical doctors and other evidence from the Isner '225 patent history as providing evidence that the claimed invention meets the utility and enablement requirements. Applicant's arguments have been fully considered but are not found to be persuasive for

the following reasons. The declarations under 37 CFR 1.132 filed 15 February 2001 are insufficient to overcome the rejection of claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374 and 376-381 based upon 35 U.S.C. §§ 101 and 112, first paragraph as set forth in the instant Office action for the following reasons. The White declaration only addresses how the Isner declarations were obtained, and thus is not sufficient to overcome the utility and enablement rejections by itself. The two Isner declarations are insufficient to overcome the utility and enablement rejections, as they are limited to reporting results of gene therapy experiments wherein naked DNA was administered to patients. No living organisms were administered, and thus the Isner declarations are irrelevant. The Wheeler declaration is insufficient to overcome the utility and enablement rejections since it does not specifically address administration of living organisms to promote soft tissue growth. Dr. Wheeler supports his opinion by reference to several publications attached as Exhibit C. None of these references report administration of a living organism to promote soft tissue growth. Similarly, the Meger declaration is insufficient to overcome the utility and enablement rejections since it does not specifically address administration of living organisms to promote soft tissue growth. Dr. Meger supports his opinion by reference to several publications attached as Exhibit C. None of these references report administration of a living organism to promote soft tissue growth. Similarly, the Lorincz declaration is insufficient to overcome the utility and enablement rejections since it does not specifically address administration of living organisms to promote soft tissue growth. Dr. Lorincz supports his opinion by reference

to several publications attached as Exhibit C. None of these references report administration of a living organism to promote soft tissue growth. Finally, the Finley declaration is insufficient to overcome the utility and enablement rejections since it does not specifically address administration of living organisms to promote soft tissue growth. Dr. Finley supports his opinion by reference to several publications attached as Exhibit C. None of these references report administration of a living organism to promote soft tissue growth.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER